UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,529	06/03/2002	Maria S Gawryl	1161.1027072	4904

21005 7590 10/01/2004

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,529	GAWRYL ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1-7-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nho et al. in view of Dodrill.

The claims are drawn to method of preserving hemoglobin in an oxygen-impermeable container. The container is an oxygen barrier foil over wrap and further comprises a foil laminate material and a polymer layer.

The reference of Nho et al. teach a method of obtaining a deoxygenated hemoglobin solution that may be utilized as a safe and effective red blood substitute in human as well as animals (see col. 13, lines 38-40). The reference teaches in order to optimize the oxygen carrying capacity of the hemoglobin, the hemoglobin must be deoxygenated to be in the deoxy Hb form (col. 8, lines 26-29). The difference between the reference and the instant application is that the reference does not

teach the specifics of the container as claimed to be used as a storage container for the hemoglobin solution.

However, Dodrill teach oriented polyester films coated packages have been used for health care packaging. The most widely used composite is OPET laminated or extrusion coated to 1.5-3.0 mil polyethylene. The reference teach that polyvinyl alcohol coated OPET film "significantly improves the oxygen barrier properties when the relative humidity (RH) is below 50%" (see page 5). PVOH coated OPET film composites can be used for products that require good oxygen barrier properties (see page 6). Similarly silicon oxide coated OPET provide an excellent oxygen and moisture barrier properties (see page 8). Specifically, the reference teaches various composites with their oxygen permeability values. The OPET composite containing PVOH and 2.0 LLDPE had a oxygen permeability value of .2 cc/100 in^2/24 hr at 73°C (see table 2, page 16). The OPET composite containing silicon oxide and 2.0 LLDPE had a oxygen permeability value of ranging from .1 to less than .003 cc/100 in^2/24 hr at 73°C (see table II, page 16 and table III, page 17). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a blood substitute as disclosed by Nho et al. and then store the blood substitute in a storage container as disclosed by Herbert al. because the bags would keep the hemoglobin in the deoxy-state, due to the low oxygen permeability of the films, and thereby increasing the storage life of ready to use hemoglobin.

It would have been further obvious to store the bag in an inert environment such as nitrogen, argon, helium atmosphere because such an atmosphere would have no oxygen molecules to oxygenate the blood thereby decreasing the life of the stored blood. Thus an inert environment would result in an increase of storage time capacity and half life of the blood.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. US 6610832. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

The claims are drawn to method of preserving a packaged deoxygenated hemoglobin blood substitute wherein the hemoglobin is stored in a package comprising an transparent laminate material and a fill laminate material that forms a chamber, wherein the laminate material includes a silicon oxide layer.

A method for preserving a deoxygenated hemoglobin blood substitute comprising maintaining the deoxygenated hemoglobin blood substitute in an oxygen barrier film over wrap that includes a transparent laminate material and a foil laminate material, wherein the transparent laminate material includes a flexed silicon oxide layer (see claim 1). The US Patent also discloses, similar to claim 2-4, that the laminate material includes a polyester layer, or low density polymer layer (see claims 2-4 of the US Patent). The difference between the US Patent and the instant application is that the US Patent teaches a "flexed silicon oxide layer" rather than a general silicon oxide layer

and the US Patent does not teach the thickness of the silicon oxide layer and oxygen permeability as claimed.

However, the MPEP states a genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Here, the instant claims are drawn to generic silicon oxide. The species flexed silicon oxide, disclosed in the US patent, read on the instant generic silicon oxide, thereby rendering the two sets of claims as being not patentably distinct from each other.

As for the layer sizes, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." MPEP 2144.05. Thus, it would have been obvious to optimize the thickness of the oxide layer to achieve the optimum level of preventing oxygen permeability.

3. Claim 1-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. US 6610832. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

The claims are drawn to method of preserving a packaged deoxygenated hemoglobin blood substitute wherein the hemoglobin is stored in a package comprising an transparent laminate material and a fill laminate material that forms a chamber, wherein the laminate material includes a silicon oxide layer.

The US Patent claims method for preserving a deoxygenated hemoglobin blood substitute comprising maintaining the deoxygenated hemoglobin blood substitute in a transparent primary package that includes a polymer material having at least one oxygen barrier component that includes ethylene vinyl alcohol, said polymer material having an oxygen permeability of less than about 0.6 cc per 100 square inches per 24 hours per atmosphere at about 25.degree. C. and an external relative humidity of about 50% (see claim 1). Note that the US Patent claims that the oxygen barrier compenent includes a silicon oxide layer (see claim 5). Furthermore, the US Patent and the instant application both claim that the polymer is either a linear low density polymer layer such as polyethylene, polypropylene and copolymers thereof (see claims 2-4 of the US patent and claims 2-5 of the instant application). Finally, the oxygen permeability claimed in the instant application is encompasses the oxygen permeability claimed in the US Patent (see claim 1 of the US patent and claim 7 of the instant application). The difference between the US Patent and the instant application is US Patent does not teach the thickness of the silicon oxide layer.

However, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." MPEP 2144.05. Thus, it would have been obvious to optimize the thickness of the oxide layer to achieve the optimum level of preventing oxygen permeability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9/23/04

Anish Gupta
Patent Examiner